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December 30, 2003

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Art Unit 1648**

Re: U.S. Utility Patent Application  
Application No. 10/670,797; Filed: September 26, 2003  
For: **Monoacylated Betulin and Dihydrobetulin Derivatives, Preparation  
Thereof and Use Thereof**  
Inventors: ALLAWAY *et al.*  
Our Ref: 1900.0400001/JMC/SMW

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Form PTO-1449 (5 sheets) listing 22 documents (AA1, AB1, AL1-AP1, AR1-AT1, AL2, AR2-AT2, AR3-AT3, AR4-AT4, AR5 and AS5);
3. A copy of 20 cited documents (AL1-AP1, AR1-AT1, AL2, AR2-AT2, AR3-AT3, AR4-AT4, AR5 and AS5); and
4. One (1) return postcard.

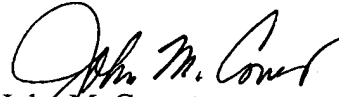
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
December 30, 2003  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



John M. Covert  
Attorney for Applicants  
Registration No. 38,759

JMC/SMW:kim  
Enclosures

SKGF\_DC1;214295.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Allaway *et al.*

Appl. No.: 10/670,797

Filed: September 26, 2003

For: **Monoacylated Betulin and  
Dihydrobetulin Derivatives, Preparation  
Thereof and Use Thereof**

Confirmation No.: 7896

Art Unit: 1648

Examiner: *To be assigned*

Atty. Docket: 1900.0400001/JMC/SMW

**Information Disclosure Statement**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of Documents AA1 and AB1 is not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 C.F.R. 1.98(a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application for all U.S. national patent applications filed after June 30, 2003." A copy of all other documents is provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following concise explanation of the relevance of the non-English language document, Document AS4, cited on Form PTO-1449:

Document AS4, Pokrovskii, A.G., et al., "Synthesis of Derivatives of Plant Triterpenes and Study of Their Antiviral and Immunostimulating Activity," *Khimiya v Interesakh Ustoichivogo Razvitiya* 9:485-491 (2001), is in the Russian language. The

relevance of Document AS4 can be ascertained by reference to an unverified English language abstract attached as Document AS5.

After a diligent effort, the month of publication could not be determined for Document AS4. For all other documents, where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

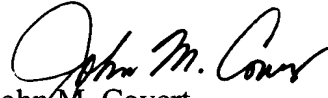
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO 1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

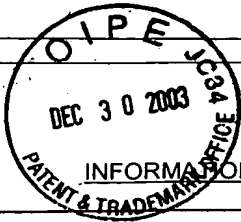
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

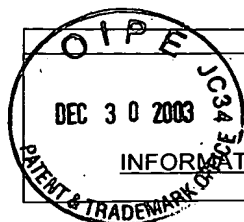


John M. Covert  
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Registration No. 38,759

Date: Dec. 30, 2003

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 FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				ATTY. DOCKET NO. 1900.0400001/JMC/SMW		APPLICATION NO. 10/670,797			
				FIRST NAMED INVENTOR Allaway <i>et al.</i>					
				FILING DATE September 26, 2003		ART UNIT 1648			
				<b>U.S. PATENT DOCUMENTS</b>					
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE		
	AA1	5,679,828	10/21/1997	Lee <i>et al.</i>			06/05/1995		
	AB1	6,172,110 B1	01/09/2001	Lee <i>et al.</i>			03/02/1999		
	AC								
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	AE								
	AF								
	AG								
	AH								
	AI								
	AJ								
	AK								
<b>FOREIGN PATENT DOCUMENTS</b>									
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION		
	AL1	WO 96/39033 A1	12/12/1996	WIPO			Yes No		
	AM1	WO 00/59492 A2	10/12/2000	WIPO			Yes No		
	AN1	WO 01/59457 A2	08/16/2001	WIPO			Yes No		
	AO1	WO 02/26761 A1	04/04/2002	WIPO			Yes No		
	AP1	WO 02/26762 A1	04/04/2002	WIPO			Yes No		
<b>OTHER (Including Author, Title, Date, Pertinent Pages, etc.)</b>									
	AR	1	Fujioka, T., and Kashiwada, Y., "Anti-AIDS Agents. 11. Betulinic Acid and Platanic Acid as Anti-HIV Principles from <i>Syzigium claviflorum</i> , and the Anti-HIV Activity of Structurally Related Triterpenoids," <i>J. Nat. Prod.</i> 57:243-247, American Chemical Society and American Society of Pharmacognosy (1994)						
	AS	1	Hashimoto, F., <i>et al.</i> , "Anti-AIDS Agents-XXVII. Synthesis and Anti-HIV Activity of Betulinic Acid and Dihydrobetulinic Acid Derivatives," <i>Bioorg. Med. Chem.</i> 5:2133-2143, Elsevier Science, Ltd. (1997)						
	AT	1	Kanamoto, T., <i>et al.</i> , "Anti-Human Immunodeficiency Virus Activity of YK-FH312 (a Betulinic Acid Derivative), a Novel Compound Blocking Viral Maturation," <i>Antimicrobial Agents Chemother.</i> 45:1225-1230, American Society for Microbiology (April 2001)						
EXAMINER						DATE CONSIDERED			
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.									



DEC 30 2003

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1900.0400001/JMC/SMWAPPLICATION NO.  
10/670,797FIRST NAMED INVENTOR  
Allaway *et al.*FILING DATE  
September 26, 2003ART UNIT  
1648

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 02/16395 A1	02/28/2002	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

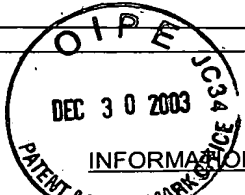
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Kashiwada, Y., <i>et al.</i> , "Betulinic Acid and Dihydrobetulinic Acid Derivatives as Potent Anti-HIV Agents," <i>J. Med. Chem.</i> 39:1016-1017, American Chemical Society (1996)
	AS	2	Kashiwada, Y., <i>et al.</i> , "Anti-AIDS Agents. 30. Anti-HIV Activity of Oleanolic Acid, Pomolic Acid, and Structurally Related Triterpenoids," <i>J. Nat. Prod.</i> 61:1090-1095, American Chemical Society and American Society of Pharmacognosy (1998)
	AT	2	Kashiwada, Y., <i>et al.</i> , "Synthesis and Anti-HIV Activity of 3-Alkylamido-3-deoxy-betulinic Acid Derivatives," <i>Chem. Pharm. Bull.</i> 48:1387-1390, Pharmaceutical Society of Japan (2000)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

 FORM PTO-1449 <b>INFORMATION DISCLOSURE STATEMENT</b>		Page 3 of 5		
		ATTY. DOCKET NO. 1900.0400001/JMC/SMW		APPLICATION NO. 10/670,797
		FIRST NAMED INVENTOR Allaway <i>et al.</i>		
		FILING DATE September 26, 2003	ART UNIT 1648	

### U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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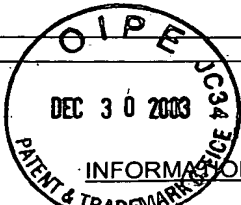
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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

### OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>3</u>	Kashiwada, Y., <i>et al.</i> , "Anti-AIDS Agents 38. Anti-HIV Activity of 3-O-Acyl Ursolic Acid Derivatives," <i>J. Nat. Prod.</i> 63:1619-1622, American Chemical Society and American Society of Pharmacognosy (2000)
	AS	<u>3</u>	Ma, C., <i>et al.</i> , "Inhibitory Effects of Ursolic Acid Derivatives from <i>Cynomorium songaricum</i> , and Related Triterpenes on Human Immunodeficiency Viral Protease," <i>Phytother. Res. (Supplement 1, 2<sup>nd</sup> Intl Symposium on Natural Drugs)</i> 12:S138-S142, John Wiley & Sons, Ltd. (1998)
	AT	<u>3</u>	Ma, C., <i>et al.</i> , "Inhibitory Effects of Constituents from <i>Cynomorium songaricum</i> and Related Triterpene Derivatives on HIV-1 Protease," <i>Chem. Pharm. Bull.</i> 47:141-145, Pharmaceutical Society of Japan (1999)

EXAMINER	DATE CONSIDERED
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		Page 4 of 5		
		ATTY. DOCKET NO. 1900.0400001/JMC/SMW		APPLICATION NO. 10/670,797
		FIRST NAMED INVENTOR Allaway <i>et al.</i>		
		FILING DATE September 26, 2003		ART UNIT 1648
INFORMATION DISCLOSURE STATEMENT				

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### FOREIGN PATENT DOCUMENTS

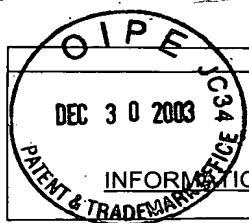
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

### OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>4</u>	Neamati, N., "A Small-molecule Antagonist of Virion Assembly," <i>Expert Opin. Investig. Drugs</i> 10:1767-1770, Ashley Publications, Ltd. (September 2001)
	AS	<u>4</u>	Pokrovskii, A.G., <i>et al.</i> , "Synthesis of Derivatives of Plant Triterpenes and Study of Their Antiviral and Immunostimulating Activity," <i>Khimiya v Interesakh Ustoichivogo Razvitiya</i> 9:485-491, Siberian Branch of the Russian Academy of Sciences (2001)
	AT	<u>4</u>	Sun, I-C., <i>et al.</i> , "Anti-AIDS Agents. 34. Synthesis and Structure-Activity Relationships of Betulin Derivatives as Anti-HIV Agents," <i>J. Med. Chem.</i> 41:4648-4657, American Chemical Society (1998)

EXAMINER	DATE CONSIDERED
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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO.	APPLICATION NO.
	1900.0400001/JMC/SMW	10/670,797
	FIRST NAMED INVENTOR	
	Allaway <i>et al.</i>	
FILING DATE		ART UNIT
September 26, 2003		1648

### U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

### OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Sun, I-C., <i>et al.</i> , "Anti-AIDS Agents. 32. Synthesis and Anti-HIV Activity of Betulin Derivatives," <i>Bioorg. Med. Chem. Lett.</i> 8:1267-1272, Elsevier Science, Ltd. (1998)
	AS	<u>5</u>	STNEasy, Accession No. 2001:541179, CAPLUS, ACS on STN (2003), English language abstract for Pokrovskii, A.G., <i>et al.</i> , "Synthesis of Derivatives of Plant Triterpenes and Study of Their Antiviral and Immunostimulating Activity," <i>Khimiya v Interesakh Ustoichivogo Razvitiya</i> 9:485-491 (2001)
	AT		

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